

### REMARKS

Claims 1-31 will be pending after entry of the foregoing amendment. Claims 1, 2, 16, 18, 19 and 20 have been amended to clarify the claimed features of Applicants' invention by adding that polymerization takes place *in situ*. Support for these amendments can be found in the specification at, for example, page 4, line 11 and page 5, line 32. Support for further amendments to claim 1 can be found in the specification at page 5, lines 30-32 to page 6, lines 1-2. New claims 24-31 have been added. Support for claim 24 can be found in the specification at page 15, lines 20-28. Support for claim 25 can be found in the specification at page 12, lines 2-3. Support for claim 26 can be found in the specification in Example 1, at pages 19-20. Support for claim 27 can be found in the specification in Example 2, at page 20. Support for claim 28 can be found in the specification in Example 3, at page 20. Support for claim 29 can be found in the specification in Example 4, at page 20-21. Support for claim 30 can be found in the specification in Example 5, at page 21. Support for claim 31 can be found in the specification in Example 6, at page 21-22. No new matter has been added.

Because the present amendments (1) do not raise new issues requiring further consideration or search, (2) do not introduce new matter, (3) materially reduce the issues for appeal, and (4) place this application into better condition for allowance, entry is appropriate under 37 C.F.R. § 1.116, and is respectfully requested.

Based on the following remarks, Applicants respectfully request reconsideration and allowance of the pending claims.

The Examiner has rejected claims 1-23 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,299,604 to Ragheb et al. or U.S. Patent No. 5,910,316 to Keefer et al. in view of U.S. Patent No. 5,849,839 to Hubbell et al. or U.S. Patent No. 5,900,433 to Igo et al. in view of U.S. Patent No. 5,849,839 to Hubbell et al.

U.S Patent No. 6,299,604 to Ragheb et al.

The Examiner states that *Ragheb et al.* provides a medical device comprising a porous layer composed of a polymer, which controls the delivery of a bioactive agent. The Examiner further states that the polymers of *Ragheb et al.* are derived from polymerizable monomers.

Applicants respectfully submit that *Ragheb et al.* does not teach the delivery of a bioactive agent bound to a polymerizable macromer, as claimed in this application. *Ragheb et al.* teaches a bioactive agent bound to a porous polymer such as polyamide, parylene or a parylene derivative. None of these polymers are polymerizable, as claimed in this application. Release of the agent in *Ragheb et al.* is through the porous polymer, not through polymerization of a macromer.

The Examiner states that *Ragheb et al.* teaches that biocompatible polymers may be applied by vapor deposition and polymerize upon condensation from the vapor phase or may be photolytically polymerizable. Applicants submit that the claims have been amended to clarify that polymerization in the present invention is *in situ*. The polymers of *Ragheb et al.* are photolytically polymerizable when preparing the device. *Ragheb et al.* does not teach a macromer composition for polymerization *in situ*.

U.S. Patent No. 5,910,316 to Keefer et al.

The Examiner states that *Keefer et al.* discloses a method of releasing NO with a NO-releasing agent, wherein the NO-releasing agent can be a polymer. The Examiner also states that *Keefer et al.* teaches that the polymer enables the controllable and predictable release of NO and that any polymer can be used for the invention. The Examiner notes that *Keefer et al.* does not specify the various regions of the monomers in the polymer.

Applicants respectfully submit that *Keefer et al.* does not teach a nitric oxide-releasing agent bound to a polymerizable macromer as claimed in the present application. *Keefer et al.* teaches a nitric oxide-releasing agent bound to a polymer such as poly(lactide/glycolide), polyethyleneimine, aminopolystyrene, polyethyleneglycol, or a mixture thereof. None of these polymers are polymerizable. Applicants submit that the claims have been amended to clarify that polymerization in the present invention is *in situ*.

U.S. Patent No. 5,900,433 to Igo et al.

The Examiner states that *Igo et al.* teaches administration of a NO and NO donor agents, and that the method of administration includes an implant which is capable of controlled-release of the bioactive agent and preferably comprising a biodegradable polymer. The Examiner further notes that *Igo et al.* does not specify the various regions of the monomers in the polymer.

*Igo et al.* teaches a nitric oxide-releasing agent bound to a biodegradable polymer for the release of NO. Claim 1 of the present invention, as amended by the current amendment, however, recites "wherein NO or the NO modulating compound is releasable from the

macromer composition following polymerization *in situ*". Thus, Applicants respectfully submit that *Igo et al.* does not teach a nitric oxide-releasing agent bound to a polymerizable macromer as claimed in the present application.

U.S. Patent No. 5,849,839 to Hubbell et al.

The Examiner states that *Hubbell et al.* provides multifunctional polymers for use in inhibiting cell adhesion, and that the polymers include biocompatible polymers, such as PVP and PVA. The Examiner further states that *Hubbell et al.* teaches that polymers exhibiting more than one manner of degradation are required in some cases.

Applicants submit that *Hubbell et al.* does not teach the delivery of a bioactive agent bound to a polymerizable macromer as claimed in the present application. *Hubbell et al.* teaches a bioactive agent bound to a biodegradable polymer for the release of NO. In contrast, claim 1 of the present invention recites "wherein NO or the NO modulating compound is releasable from the macromer composition following polymerization *in situ*".

U.S. Patent No. 6,262,206 to Nesvadba et al.

The Examiner states that *Nesvadba et al.* teaches that polymerization can be started and stopped at will and that it is possible to carry out additional polymerizations with the same or different monomers to prepare multi-block copolymers. Applicants respectfully submit that *Nesvadba et al.* does not teach a biocompatible composition, nor does it teach polymerization *in situ*.

Therefore, it is seen that none of the references teach the composition or method of the present invention. Applicants respectfully submit that it could not have been obvious to

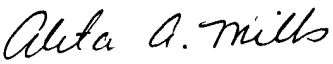
one having ordinary skill in the art at the time the invention was made to apply or modify any of the teachings of the cited references to prepare the composition or practice the method as claimed in the present invention.

**CONCLUSION**

In light of the amendment and the above remarks, Applicants are of the opinion that the Office Action has been completely responded to and that the application is now in condition for allowance. Such action is respectfully requested.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview a telephone call to the undersigned attorney at (404) 815-6409 is respectfully solicited.

Respectfully submitted,  
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Attorney Docket No. 47400-0100 (47400/252658)